JUN 2 7 2000

Section 2: 510(k) Summary of Safety and Effectiveness

Date: April 21, 2000

Submitter: GE Marquette Medical Systems
13000 Executive Dr.
Sugar Land, TX 77478 USA

Contact Person: J. Ian McDonald
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GE Marquette Medical Systems
13000 Executive Dr.
Sugar Land, TX 77478 USA
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Device: Trade Name: MAC-LAB System and CardioLab EP System

Common/Usual Name: Catheterization Lab System and Electrophysiology Lab System

Classification Names:

870.1425	Programmable Diagnostic Computer (DQK, Class II, 74 CV)
870.2050	Biopotential Amplifier and Signal Conditioner (DRR, Class II, 74 CV)
870.2340	Electrocardiograph (DPS, Class II, 74 CV)
870.1110	Blood Pressure Computer (DSK, Class II, 74 CV)

Predicate Devices: GE Marquette MAC-LAB Cardiac Catheterization Laboratory System
K992948, SE date: 29 November 1999

GE Marquette Prucka CardioLab EP System
K993414, SE date: 7 April 2000

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Section 2: 510(k) Summary of Safety and Effectiveness (cont.)

Device Description: The MAC-LAB System:

The MAC-LAB System is a microprocessor based data acquisition system used during cardiac catheterization procedures. The MAC-LAB system, via various models of the GE Marquette TRAM module (K921669) and amplifier module, acquires patient data which may include surface ECG, invasive and non-invasive blood pressure, blood oxygen saturation via pulse oximetry, respiration, and temperature. The TRAM module is housed in a dedicated front end chassis called the remote acquisition unit (RAU). The MAC-LAB System joins together the TRAM module and amplifier module with computer processors, software, high resolution display monitors, power supply, laser printer, keyboard and mouse. Digital data is transmitted, via cable, from the TRAM module and/or amplifier module to the computer for processing. Major functions of the software include data acquisition and display, data storage, reporting of data, and transmission of data to other information systems via LAN.

The CardioLab EP System:

The CardioLab EP System is a microprocessor based data acquisition system used during electrophysiology procedures to acquire ECG, intracardiac signals, and pressure signals via amplifier module. Digital data is also acquired from other devices such as RF generators, fluoro video systems and the GE Marquette TRAM module. The ECG, intracardiac and pressure data are acquired by an amplifier that is connected to the patient by third-party devices such as ECG leadwires and catheters. The amplifier filters, amplifies, digitizes and transmits the data to the computer via fiber optic cable. The computer stores the data on optical disks, displays the data on the video monitors, allows the user to perform basic signal measurements, and prints out waveforms on a laser printer or continuous paper recorder. Major functions of the software include data acquisition and display, data storage, reporting of data, and transmission of data to other information systems via LAN.

Section 2: 510(k) Summary of Safety and Effectiveness (cont.)

Intended Use: MAC-LAB System:

The MAC-LAB System is intended for use under the direct supervision of a licensed healthcare practitioner to monitor and/or calculate and/or record cardiovascular data from patients as they undergo cardiac catheterization. Cardiovascular data may be manually entered or acquired via an interfaced GE Marquette TRAM modules (k921669), MUSE cardiovascular system and other interfaced information systems. Data includes: ECG waveforms, heart rate, pulse oximetry (SpO_2), respiration rate, valve gradients and areas, cardiac output, hemodynamic measurements, invasive and noninvasive blood pressure, procedural information, and optional intracardiac electrocardiogram (IECG). This information can be displayed, trended, stored, printed and/or transmitted to other networked hospital information systems.

Applicable to pediatric/adult patients requiring cardiac/circulatory system catheterization.

Intended for use in catheterization and related cardiovascular specialty labs.

CardioLab EP System:
The intended use of the CardioLab EP System is to acquire, filter, digitize, amplify, display, and record electrical signals obtained during electrophysiological studies and related procedures conducted in an electrophysiological laboratory. Signal types acquired include ECG signals, direct cardiac signals, and pressure recordings. Physiological parameters such as diastolic, systolic, and mean blood pressure, heart rate, and cycle length may be derived from the signal data, displayed and recorded. The system allows the user to monitor the acquisition of data, review the data, store the data, perform elementary caliper-type measurements of the data, and generate reports on the data. Additionally, the system may acquire, amplify, display, and record data received from other medical devices typically used during these procedures, such as imaging devices and RF generators.
The CardioLab EP system does not control the delivery of energy, administer drugs, perform any life-supporting or life-sustaining functions, or analyze physiological data or other data acquired during an EP procedure. It does not transmit alarms or arrhythmias, and does not have arrhythmia detection capabilities.

Technology: The proposed MAC-LAB System and CardioLab EP System employ the same functional technology as the predicate devices.

Section 2: 510(k) Summary of Safety and Effectiveness (cont.)

Test Summary: The MAC-LAB System and CardioLab EP System comply with the voluntary standards as detailed in Section 9 of this submission. The following quality assurance measures are applied to the development of the Systems:

- Requirements specification review
- Code inspections
- Software and hardware testing
- Safety testing
- Environmental testing
- Final validation

Conclusion: The results of these measurements demonstrate that the MAC-LAB system and the CardioLab EP System are as safe, as effective, and perform as well as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 27 2000

Mr. J. Ian McDonald
RA/QA Manager, Prucka Center
GE Marquette Medical Systems
13000 Executive Dr.
Sugar Land, TX 77478

Re: K001305
GE Marquette Medical Systems MAC-LAB System and CardioLab EP system
Regulatory Class: II (two)
Product Code: 74 DQK
Dated: April 21, 2000
Received: April 24, 2000

Dear Mr. McDonald:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket

notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices
and Radiological Health

Enclosure

510(k) Number (if known): K001305

Device Name: MAC-LAB System and CardioLab EP System

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Note: Catheterization devices are *not* provided or offered for use with the MAC-LAB System and CardioLab EP System.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milleran

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K001305

(Optional Format 3-10-98)

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